1. Scientific Abstract

This is an uncontrolled, non-randomized trial to evaluate safety, toxicity and feasibility of a novel vaccine, consisting of an irradiated, semi-allogeneic human SCCHN cell line genetically-modified to secrete IL-2 and transduced with autologous tumor-derived DNA. Briefly, the plan is to enroll 24 patients with recurrent advanced carcinoma of the oral cavity or oropharynx over a period of 3 to 4 years in a phase I protocol. The patients will undergo surgery, and a portion of the primary tumor specimen will be obtained to serve as a source of tumor DNA. The vaccine will be prepared as described below and administered intradermally to a site (or more than one site) on the left arm. Only those HLA-A2+ patients who have normal DTH responses (induration >5mm) to at least one of four recall antigens will be eligible to receive the vaccine. The 24 patients will be divided into 3 cohorts, the first cohort of 5 patients to receive $5x10^6$ irradiated vaccine cells. If there is no grade 3 or 4 toxicity, the second group of 7 patients will receive $1x10^7$ cells, and if there is still no evidence of toxicity, the third cohort of 12 patients will be vaccinated with $5x10^7$ cells. All patients will be monitored by IFN-γ secretion in ELISPOT assays prior to and after vaccination for the frequency of T-cells responsive to autologous tumor and to the vaccine. The patients will also be evaluated before and after vaccination for the capability of their T cells to respond to activating signals delivered via the T cell receptor (TcR).

Primary Objective: To determine the safety and feasibility of immunization of patients with carcinoma of the oral cavity or oropharynx with an IL-2-secreting, irradiated, semi-allogeneic human oral carcinoma cell line transfected with DNA obtained from the patient's own cancer cells.

Secondary Objective: To evaluate the ability of the DNA-based vaccine to induce immune responses to the autologous tumor.